SEP 2 3 2005

Premarket Notification [510(k)] Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is : K050448

Company: Horiba ABX
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Contact Person: Tim Lawton (tlawton@fr.abx.fr)

Date Prepared: February 16th, 2005

(a) Device Name:

Trade/Proprietary Name:	**Chromopep PC 2.5 or Chromopep PC 5**
Common or Usual Name:	Protein C chromogenic assay
Device Class	Class II
Classification Name:	Test, Quantitative factor deficiency (§864.7290)
Product Code:	GCP

(b) Device Name:

Trade/Proprietary Name:	**Chromopep AT 2.5 or Chromopep AT 5**
Common or Usual Name:	Antithrombin chromogenic assay
Device Class	Class II
Classification Name:	Antithrombin quantitation (§864.7060)
Product Code:	JBQ

Substantial Equivalence:

Chromopep PC
The **Chromopep PC** is substantially equivalent to the predicate device **Chromocheck Protein C** of Precision BioLogic **(K023990).**

Chromopep AT
The **Chromopep AT** is substantially equivalent to the predicate device **Chromocheck Antithrombin AT** of Precision BioLogic **(K023991).**

Description:

Chromopep PC is a chromogenic assay consisting of a synthetic substrate and Protein C activator.

Chromopep AT is a chromogenic assay consisting of a synthetic substrate, Factor Xa, and a Tris Heparin Buffer.

Intended Use :

Chromopep PC is intended for use as an *in vitro* chromogenic assay for the quantitative determination of Protein C activity in citrated human plasma.

Chromopep AT is intended for use as an *in vitro* chromogenic assay for the quantitative determination of antithrombin activity in citrated human plasma.

Determination of substantial equivalence :

Table I : Comparison between Predicate Device & Chromopep PC

Parameter	Predicate device:	Device:
Device Name	Chromocheck Protein C (K023990)	Chromopep PC
Intended Use	Test, quantitative factor deficiency	Test, Quantitative factor deficiency
Analytes	Protein C activity	Protein C activity
Component Reagent Matrices	**Reagent 1 :** Protein C activator in a distilled water matrix (0.65 IU) **Reagent 2 :** Chromogenic substrate in a distilled water matrix	**Reagent 1 :** Protein C activator in a distilled water matrix (0.65 IU) **Reagent 2 :** Chromogenic substrate in a distilled water matrix
Format	Lyophilized	Lyophilized
Packaging	Chromocheck Protein C 25 4 x Protein C Activator (0.65IU) 4 x Substrate (4mg) (Reconstituted volume – 2.5ml) Chromocheck Protein C 50 4 x Protein C Activator (1.30IU) 4 x Substrate (8mg) (Reconstituted volume – 5.0ml)	Chromopep PC 2.5 4 x Protein C Activator (0.65IU) 4 x Substrate (4mg) (Reconstituted volume – 2.5ml) Chromopep PC 5 4 x Protein C Activator (1.30IU) 4 x Substrate (8mg) (Reconstituted volume – 5.0ml)

Table II : Comparison between Predicate Device & Chromopep AT

Parameter	Predicate device:	Device:
Device Name	Chromocheck Antithrombin (K023991)	Chromopep AT
Intended Use	Antithrombin quantitation	Antithrombin quantitation
Analytes	Antithrombin	Antithrombin
Component Reagent Matrices	**Reagent 1 :** Factor Xa – Bovine Factor Xa in a Tris Heparin Buffer matrix **Reagent 2 :** Chromogenic substrate in a distilled water matrix **Reagent 3 :** Tris Heparin Buffer	**Reagent 1 :** Factor Xa – Bovine Factor Xa in a Tris Heparin Buffer matrix **Reagent 2 :** Chromogenic substrate in a distilled water matrix **Reagent 3 :** Tris Heparin Buffer
Format	Lyophilized	Lyophilized
Packaging	Chromocheck Antithrombin 25 4 x Factor Xa (5µg) 4 x Substrate (3.75mg) 4 x 5mL Tris Heparin Buffer Chromocheck Antithrombin 50 4 x Factor Xa (10µg) 4 x Substrate (7.5mg) 4 x 10mL Tris Heparin Buffer	Chromopep AT 2.5 4 x Factor Xa (5µg) 4 x Substrate (3.75mg) 4 x 5mL Tris Heparin Buffer Chromopep AT 5 4 x Factor Xa (10µg) 4 x Substrate (7.5mg) 4 x 10mL Tris Heparin Buffer

Conclusions :
Chromopep PC can be considered as substantially equivalent to Chromocheck Protein C.

Chromopep AT can be considered as substantially equivalent to Chromocheck Antithrombin.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 2 3 2005

Mr. Tim Lawton
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FRANCE

Re: k050448
Trade/Device Name: Chromopep PC 2.5 or Chromopep PC 5 and
Chromopep AT 2.5 or Chromopep AT 5
Regulation Number: 21 CFR § 864.7290
Regulation Name: Factor Deficiency Test
Regulatory Class: II
Product Code: GGP, JBQ
Dated: September 2, 2005
Received: September 6, 2005

Dear Mr. Lawton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Robert L. Becker, Jr., MD, Ph.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050448

Device Name: CHROMOPEP AT

Indications For Use:

CHROMOPEP AT is intended for use as an *in vitro* chromogenic assay for the quantitative determination of antithrombin activity in citrated human plasma.

Prescription Use ___V___ AND/OR Over-The-Counter Use

_____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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Indications for Use

510(k) Number (if known): K050448

Device Name: CHROMOPEP PC

Indications For Use:

CHROMOPEP PC is intended for use as an *in vitro* chromogenic assay for the quantitative determination of Protein C activity in citrated human plasma.

Prescription Use ___√___ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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